

# FIG. IA

1/2

	-4 <sup>2</sup>	-2 <sup>0</sup>	-1 <sup>2</sup>	1	7	10	17	24	31	38	45	*
Day of Study	to to	to 3	10 3									
Week of Study	-30	-3		1	2	3	4	5	6	7		
Month of Study						1	2	3	4	5	6	7
Surgery	X											
Informed Consent	X											
Randomize	X											
Cyclophosphamide		X	X	X	X	X	X	X	X	X	X	
BCG		X	X	X	X	X	X	X	X	X	X	
Vaccine	X	X	X	X	X	X	X	X	X	X	X	*
History/Physical Exam	X	X	X	X	X	X	X	X	X	X	X	*
Vital Signs	X	X	X	X	X	X	X	X	X	X	X	*
Performance Status	X	X	X	X	X	X	X	X	X	X	X	*
Routine Labs <sup>#</sup>	X	X	X	X	X	X	X	X	X	X	X	
Pregnancy (HCG)	X											
Hepatitis/HIV	X											
Chest X-Ray										Xe	Xe	*
CT or MRI										Xe	Xe	*

A

# FIG. 1B

A ————— A

- † This can be extended up to -56 days only if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization
  - \* History/Physical Exam, Vital Signs, Performance Status, Routine Labs, Chest X-Ray q2 months in year 2, q3 months in year 3, then q6 months through year 5; CT or MRI at 18, 24, and 36 months (chest x-ray omitted if CT/MRI scheduled)
- XA 0.1mL of a 1:10 dilution of Tice BCG (Tice-A) mixed with vaccine
- XB 0.1 mL of a 1:100 dilution of Tice BCG (Tice-B) mixed with vaccine
- XC 0.1 mL of a 1:1000 dilution of Tice BCG (Tice-C) mixed with vaccine
- ‡ This can be extended up to -34 days if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization
- †† Routine Labs: hematology (CBC with differential, platelet count), BUN or creatinine, LDH, SGOT, alkaline phosphatase, electrolytes
- <e End of Treatment Month